

May 30, 2001

Geneva Pharmaceuticals, Inc.
Attention: Beth Brannan
2555 W. Midway Blvd.
Broomfield, CO 80038-0446

Dear Madam:

This is in reference to your abbreviated new drug application dated August 4, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ciprofloxacin Tablets USP, 100 mg, 250 mg, 500 mg, and 750 mg.

Reference is also made to your amendments dated February 22, April 16, and May 17, 2001.

We have completed the review of this abbreviated application and have concluded that based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug product. The determination is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product referenced in your application, Cipro Tablets of Bayer Corporation, is subject to periods of patent protection which currently expire on December 9, 2003, (U.S. Patent 4,670,444, the '444 patent), and February 15, 2011, (U.S. Patent 5,286,754, the '754 patent). Your application contains a Paragraph IV Certification to the '754 patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use or sale of this drug product will not infringe the '754 patent. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated application shall be made effective immediately unless an action for patent infringement is brought

before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received by the owner of the new drug application (NDA) for the reference listed drug product, Cipro Tablets, and the patent holder. You have notified the Agency that Geneva Pharmaceuticals Inc. (Geneva) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for infringement against the '754 patent was brought against Geneva within the statutory forty-five day period. However, your application also contains a Paragraph III Certification to the '444 patent under Section 505(j)(2)(A)(vii)(III) of the Act. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the expiration of the '444 patent, i.e., currently December 9, 2003.

Because the Agency is granting a tentative approval for this application, please submit an amendment 90 days prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. Alternatively, an amendment should be submitted stating that no changes have been made to the terms of this application since the date of this tentative approval letter. This amendment should be designated clearly in your cover letter as a MINOR AMENDMENT. In addition to, or instead of, this amendment, the Agency may request at any time prior to the date of final approval of this application, that you submit an amendment containing the information described above. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any changes in the conditions outlined in this abbreviated application, as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to agency review before final approval of the application will be made.

The drug product that is the subject of this abbreviated application may not be marketed without final agency approval under Section 505 of the Act. The introduction or delivery for introduction of this drug product into interstate commerce before the final approval date is prohibited under Section 501 of the Act. Also, until the agency issues the final approval

letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list, the "Orange Book".

Should you believe that there are grounds for issuance of the final approval letter prior to December 9, 2003, you should amend your application accordingly.

At the time you submit any amendments, you should contact Ms. Ruby Yu, R.Ph., Project Manager, at (301) 827-5848, for further instructions.

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research